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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,631	03/24/2004	Nathan Andrew Shapira	UF-368XC1	8943
23557 7590 10/09/2007 SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950			EXAMINER WANG, SHENGJUN	
			ART UNIT 1617	PAPER NUMBER
			MAIL DATE 10/09/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/809,631

**Applicant(s)**

SHAPIRA ET AL.

**Examiner**

Shengjun Wang

**Art Unit**

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-24 and 32-47 is/are pending in the application.
- 4a) Of the above claim(s) 4,5,8-10,16,17,20-22,35,36 and 39-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,6,7,11-15,18,19,23,24,32-34,37,38 and 42-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application  |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                           |

### DETAILED ACTION

1. Applicant's election without traverse of invention group I, claims 1-24, and 32-47 in the reply filed on July 11, 2007 is acknowledged.

2. Claims 4, 5, 8-10, 16-17, 20-22, 35-36, 39-41, are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on July 11, 2007. Also see the interview summary for the particular compound of 5-HT<sub>2C</sub> antagonists.

3. Applicant's election without traverse of mirtazapine as the 5-HT<sub>2C</sub> affecting compounds, and injection of botulinum as the secondary medicament in the reply filed on July 11, 2007 and during the interview conducted on September 17, 2007 is acknowledged.

4. The claims have been examined insofar as they read on the elected species.

### *Claim Rejections 35 U.S.C. 102*

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 32-34, and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Waldinger et al. (NL 1012954 ).

7. Waldinger et al. treated patients with mirtazapine and thereby alleviating symptoms of perspiration. See, particularly, the abstract and the examples.

8. Claims 32-34, and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Waldinger et al. (Maturitas, 2000, vol. 36, pages 165-168)

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9. Waldinger et al. treated patients suffering from hot flushing and perspiration with mirtazapine. See, particularly, the abstract at page 165, and the case report at page 166.

***Claim Rejections 35 U.S.A. 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1-3, 6-7, 13-15, 18-19, 32-34, 37-38, 44-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Waldinger et al. (NL 1012954, and Maturitas, 2000, vol. 36, pages 165-168), in further view of Andrews et al. (WO 01/52855).

12. Waldinger et al. teaches a method of treating patients suffering hot flushing and perspiration with mirtazapine. See, the abstract of NL 1012954 and Maturitas. Waldinger et al. discloses that mirtazapine is particularly effective in alleviating perspiration. See, particularly the cases in Maturitas.

13. Waldinger et al. do not teach expressly the treatment of primary hyperhidrosis or idiopathic hyperhidrosis, or the particular dosage form of mirtazapine.

However, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to treat idiopathic hyperhidrosis patients with mirtazapine for alleviating perspiration.

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A person of ordinary skill in the art would have been motivated treat idiopathic hyperhidrosis patients for alleviating perspiration with mirtazapine because mirtazapine is known to be useful in alleviating perspiration. One of ordinary skill in the art would have reasonably expected that mirtazapine would be symptomatically useful for treating perspiration caused by any etiologies as it has been shown that mirtazapine is particularly effective in alleviating perspiration. Further, Andrews reveals that mirtazapine is an old and well-known therapeutical agent and may be formulated to conventional dosage forms for oral, parenteral, topical administrations. See, particularly, page 1, lines 16-19, page 8, line 4-38. Therefore, making a particular dosage form, such as liposome, or selecting a particular administration method for mirtazapine would have been within the purview of ordinary skill in the art. Finally, it is noted that perspiration for patient with hyperhidrosis happens periodically, the treatment as disclosed by Waldinger et al. do not require the administration be carried out at the time of perspiration, therefore, would meet the limitation “prophylactically” recited in claims 32.

Claims 1-3, 6-7, 13-15, 18-19, 32-34, 37-38, 44-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Waldinger et al. (NL 1012954, and Maturitas, 2000, vol. 36, pages 165-168), in view of Davidson et al. (IDS), and in further view of Andrews et al. (WO 01/52855).

14. Waldinger et al. teaches a method of treating patients suffering hot flushing and perspiration with mirtazapine, a serotonin antagonist. See, the abstract of NL 1012954 and Maturitas. Waldinger et al. discloses that mirtazapine is particularly effective in alleviating perspiration. See, particularly the cases in Maturitas.

15. Waldinger et al. do not teach expressly the treatment of primary hyperhidrosis or idiopathic hyperhidrosis.

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However, Davidson teaches that fluoxetine an antidepressant and serotonin antagonist is effective for reduce the symptoms of hyperhidrosis in patients of social anxiety disorders and suggest serotonergic mechanism is associated with the hyperhidrosis. See, particularly, the abstract at page 1327, and the discussion and conclusion at pages 1330-1331.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to treat idiopathic hyperhidrosis patients with serotonin antagonist, such as mirtazapine for alleviating perspiration.

A person of ordinary skill in the art would have been motivated to treat idiopathic hyperhidrosis patients for alleviating perspiration with mirtazapine because serotonin antagonists, mirtazapine in particular, are known to be useful in alleviating perspiration. One of ordinary skill in the art would have reasonably expected that mirtazapine would be symptomatically useful for treating perspiration caused by any etiologies as it has been shown that mirtazapine is particularly effective in alleviating perspiration. Further, Andrews reveals that mirtazapine is an old and well-known therapeutical agent and may be formulated to conventional dosage forms for oral, parenteral, topical administrations. See, particularly, page 1, lines 16-19, page 8, line 4-38. Therefore, making a particular dosage form, such as liposome, or selecting a particular administration method for mirtazapine would have been within the purview of ordinary skill in the art. Finally, it is noted that perspiration for patient with hyperhidrosis happens periodically, the treatment as disclosed by Waldinger et al. do not require the administration be carried out at the time of perspiration, therefore, would meet the limitation “prophylactically” recited in claims 32.

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16. Claims 11, 12, 23, 24, 42, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Waldinger et al. (NL 1012954, and Maturitas, 2000, vol. 36, pages 165-168), in further view of Andrews et al. (WO 01/52855) for reasons discussed above, and in further view of Saadia et al. (IDS).

Waldinger et al. and Andrews as a whole do not teach expressly the further injection of botulinum.

However, Saadia et al. teaches that local intradermal injection of botulinum is known to be useful for treating hyperhidrosis.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to further incorporate a step of injection botulinum for treatment of hyperhidrosis.

A person of ordinary skill in the art would have been motivated to further incorporate a step of injection botulinum for treatment of hyperhidrosis because it is prima facie obvious to combine two compositions each of which is taught in the prior art to be useful for same purpose in order to form third composition (or method of using the same) that is to be used for very the same purpose; idea of combining them flows logically from their having been individually taught in prior art; See In re Kerkhoven, 205 USPQ 1069.

17. Claims 11, 12, 23, 24, 42, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Waldinger et al. (NL 1012954, and Maturitas, 2000, vol. 36, pages 165-168), in view of Davidson et al. (IDS), and in further view of Andrews et al. (WO 01/52855) for reasons discussed above, and in further view of Saadia et al. (IDS).

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Waldinger et al. Davidson et al. and Andrews as a whole do not teach expressly the further injection of botulinum.

However, Saadia et al. teaches that local intradermal injection of botulinum is known to be useful for treating hyperhidrosis.

Therefore, it would have been prima-facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to further incorporate a step of injection botulinum for treatment of hyperhidrosis.

A person of ordinary skill in the art would have been motivated to further incorporate a step of injection botulinum for treatment of hyperhidrosis because it is prima facie obvious to combine two compositions each of which is taught in the prior art to be useful for same purpose in order to form third composition (or method of using the same) that is to be used for very the same purpose; idea of combining them flows logically from their having been individually taught in prior art; See In re Kerkhoven, 205 USPQ 1069.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications



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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Shengjun Wang  
Primary Examiner  
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